UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	Docket No. 9297
Upsher-Smith Laboratories, Inc. a corporation,	)	
and	)	
American Home Products Corporation, a corporation.	)	

AMERICAN HOME PRODUCTS CORPORATION'S
FIRST SET OF REQUESTS FOR ADMISSIONS
TO FEDERAL TRADE COMMISSION

Pursuant to FTC Rule of Practice § 3.32, 16 C.F.R. § 3.32, American Home Products Corporation submits its First Set of Requests for Admissions to the Federal Trade Commission. The Federal Trade Commission is requested to respond in writing to the following requests for admissions within twenty (20) days of service thereof.

DEFINITIONS

A. As used herein, "FTC," "Commission," "Complaint Counsel," "you," or "your" means the United States Federal Trade Commission, including its employees, agents, attorneys, consultants, representatives, officers, and all other persons acting on its behalf.

B. As used herein, "AHP" means respondent American Home Products Corporation, its predecessors, successors, assigns and present and/or former affiliates, corporate parents, divisions, or subsidiaries, including ESI Lederle, and any of its respective officers, directors, employees, partners, agents, attorneys, or any person acting on its behalf.

C. As used herein, "Schering" means respondent Schering-Plough Corporation, its predecessors, successors, assigns and present and/or former affiliates, corporate parents, divisions, or subsidiaries and any of its respective officers, directors, employees, partners, agents, attorneys, or any person acting on its behalf.

D. As used herein, "Upsher" means respondent Upsher-Smith Laboratories, Inc., its predecessors, successors, assigns and present and/or former affiliates, corporate parents, divisions, or subsidiaries and any of its respective officers, directors, employees, partners, agents, attorneys, or any person acting on its behalf.

E. As used herein, the "'743 patent" means U.S. Patent No. 4,863,743 issued to Key Pharmaceuticals, Inc. on September 5, 1989.

F. As used herein, "K-Dur 20" means the 20 milliequivalent (20 mEq) potassium chloride supplement sold under that brand name by respondent Schering-Plough Corporation.

G. As used herein, "FDA" means the United States Food and Drug Administration, including without limitation its employees, scientists, technicians, agents, examiners and laboratories.

H. As used herein, "the Patent Infringement Litigation" means the action captioned Key Pharmaceuticals, Inc. v. ESI-Lederle, Inc., Case No. 96-CV-1219, which was filed in the United States District Court for the Eastern District of Pennsylvania.

I. As used herein, the term "the Settlement Agreement" means the settlement agreement, dated June 19, 1998, that was entered into between AHP, ESI, Schering Corporation, and Key Pharmaceuticals, Inc.

J. As used herein, "the European License Agreement" means the license agreement, dated June 19, 1998, that was entered into between AHP, ESI, and Schering-Plough, Ltd.

K. As used herein, "person" means any natural person, firm, partnership, corporation, incorporated association, organization, joint venture, cooperative, governmental body or other form of legal entity.

L. As used herein, "NDA" mean an application submitted to the United States Food and Drug Administration seeking regulatory approval to market a new drug, pursuant to 21 CFR 314.50.

M. As used herein, "Pitofsky Speech" means Robert Pitofsky, Antitrust and Intellectual Property: Unresolved Issues at the Heart of the New Economy, Remarks before the Berkeley Center for Law and Technology "Antitrust, Technology and Intellectual Property" conference, Berkeley, CA (March 2, 2001).

N. As used herein, "Leary Speech" means Thomas B. Leary, Antitrust Issues in Settlement of Pharmaceutical Patent Disputes, Remarks before the Northwestern University School of Law Sixth Annual Health Care Antitrust Forum, Chicago, IL (Nov. 3, 2000).

O. As used herein, "Anthony Speech" means Sheila F. Anthony, Riddles and Lessons from the Prescription Drug Wars: Antitrust Implications of Certain Types of Agreements Involving Intellectual Property, Remarks before the ABA "Antitrust and Intellectual Property: The Crossroads" Program, San Francisco, CA (June 1, 2000).

P. As used herein, "FTC Testimony" means Prepared Statement of the Federal Trade Commission on "Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements," before the Committee on the Judiciary, United States Senate, May 24, 2001.

Q. As used herein, "Abbott Consent" means the Decision and Order In the Matter of Abbott Laboratories, Docket No. C-3946, issued by the Federal Trade Commission on May May 22, 2000.

R. As used herein, "Hoechst Consent" means the Decision and Order In the Matter of Hoechst Marion Roussel, Inc., Docket No. C-9293, issued by the Federal Trade Commission on May 8, 2001.

REQUESTS FOR ADMISSIONS

1. You have no evidence to support that any person asked AHP after January 1998 to conduct a substitutability study for a potassium chloride product with respect to K-Dur 20.

2. No person asked AHP after January 1998 to conduct a substitutability study for a potassium chloride product with respect to K-Dur 10 or K-Dur 20.

3. You have no evidence to support that any person asked AHP after January 1998 to sponsor a substitutability study for a potassium chloride product with respect to K-Dur 10 or K-Dur 20.

4. No person asked AHP after January 1998 to sponsor a substitutability study for a potassium chloride product with respect to K-Dur 10 or K-Dur 20.

5. You have no evidence to support that any person asked AHP after January 1998 to file a substitutability study for a potassium chloride product with respect to K-Dur 10 or K-Dur 20.

6. No person asked AHP after January 1998 to file a substitutability study for a potassium chloride product with respect to K-Dur 10 or K-Dur 20.

7. You have no evidence to support that any person asked AHP after January 1998 to support a substitutability study for a potassium chloride product with respect to K-Dur 10 or K-Dur 20.

8. No person asked AHP after January 1998 to support a substitutability study for a potassium chloride product with respect to K-Dur 10 or K-Dur 20.

9. You have no evidence to support that if any person had asked AHP after January 1998 to conduct, sponsor, support or file a substitutability study for a potassium chloride product with respect to K-Dur 10 or K-Dur 20, AHP would have done so.

10. You have no evidence to support that any person asked AHP after January 1998 to conduct a study of the bioequivalence or therapeutic equivalence of a potassium chloride product to K-Dur 10 or K-Dur 20.

11. No person asked AHP after January 1998 to conduct a study of the bioequivalence or therapeutic equivalence of a potassium chloride product to K-Dur 10 or K-Dur 20.

12. You have no evidence to support that any person asked AHP after January 1998 to sponsor a study of the bioequivalence or therapeutic equivalence of a potassium chloride product to K-Dur 10 or K-Dur 20.

13. No person asked AHP after January 1998 to sponsor a study of the bioequivalence or therapeutic equivalence of a potassium chloride product to K-Dur 10 or K-Dur 20.

14. You have no evidence to support that any person asked AHP after January 1998 to file a study of the bioequivalence or therapeutic equivalence of a potassium chloride product to K-Dur 10 or K-Dur 20.

15. No person asked AHP after January 1998 to file a study of the bioequivalence or therapeutic equivalence of a potassium chloride product to K-Dur 10 or K-Dur 20.

16. You have no evidence to support that any person asked AHP after January 1998 to support a study of the bioequivalence or therapeutic equivalence of a potassium chloride product to K-Dur 10 or K-Dur 20.

17. No person asked AHP after January 1998 to support a study of the bioequivalence or therapeutic equivalence of a potassium chloride product to K-Dur 10 or K-Dur 20.

18. You have no evidence to support that if any person had asked AHP after January 1998 to conduct, sponsor, support or file a study of the bioequivalence or therapeutic equivalence of a potassium chloride product to K-Dur 10 or K-Dur 20, AHP would have done so.

19. You have no evidence to support that any person that would have sought FDA approval to market a generic version of K-Dur 20 did not do so because of Section 2.9 in the Settlement Agreement.

20. No person that would have sought FDA approval to market a generic version of K-Dur 20 did not do so because of Section 2.9 in the Settlement Agreement.

21. At the time of the Settlement Agreement, there was a possibility that AHP could have lost the Patent Infringement Litigation if it continued the Patent Infringement Litigation.

22. At the time of the Settlement Agreement, it may have been more likely than not that AHP would have lost the Patent Infringement Litigation if it continued the Patent Infringement Litigation.

23. In January 1998, there was a possibility that AHP could have lost the Patent Infringement Litigation if it continued the Patent Infringement Litigation.

24. In January 1998, it may have been more likely than not that AHP would have lost the Patent Infringement Litigation if it continued the Patent Infringement Litigation.

25. As of January 1998, AHP was not confident that it would prevail in the Patent Infringement Litigation if it continued the Patent Infringement Litigation.

26. As of June 1998, AHP was not confident that it would prevail in the Patent Infringement Litigation if it continued the Patent Infringement Litigation.

27. As of January 1998, AHP believed it more likely than not that it would lose the Patent Infringement Litigation if it continued the Patent Infringement Litigation.

28. As of June 1998, AHP believed it more likely than not that it would lose the Patent Infringement Litigation if it continued the Patent Infringement Litigation.

29. You have no evidence that as of January 1998, AHP was confident that it would prevail in the Patent Infringement Litigation if it continued the Patent Infringement Litigation.

30. You have no evidence that as of June 1998, AHP was confident that it would prevail in the Patent Infringement Litigation if it continued the Patent Infringement Litigation.

31. You have no evidence that as of January 1998, AHP believed it more likely than not that it would prevail in the Patent Infringement Litigation if it continued the Patent Infringement Litigation.

32. You have no evidence that as of June 1998, AHP believed it more likely than not that it would prevail in the Patent Infringement Litigation if it continued the Patent Infringement Litigation.

33. No court has ruled that the '743 patent is invalid or unenforceable.

34. No court has ruled that there was a substantial likelihood that AHP would have prevailed in the Patent Infringement Litigation.

35. You have no evidence that there was a substantial likelihood that AHP would have prevailed in the Patent Infringement Litigation.

36. Schering's filing of the Patent Infringement Litigation was not objectively baseless.

37. The Patent Infringement Litigation was a genuine dispute about intellectual property.

38. At the time of execution of the Settlement Agreement, the benefits Schering obtained from the Settlement Agreement included the expected value of Scherng's avoided litigation costs.

39. At the time of execution of the Settlement Agreement, the benefits Schering obtained from the Settlement Agreement included the expected value of the European License Agreement.

40. Absent settlement of the Patent Infringement Litigation, Schering would have incurred additional costs in conducting the Patent Infringement Litigation.

41. Absent settlement of the Patent Infringement Litigation, Schering may have incurred substantial additional costs in conducting the Patent Infringement Litigation.

42. The value to AHP of the license to the '743 patent contained in the Settlement Agreement may have been greater if AHP was not able to obtain preliminary FDA approval to market its generic K-Dur product than if AHP was able to obtain preliminary FDA approval to market its generic K-Dur product.

43. The value to AHP of the license to the '743 patent contained in the Settlement Agreement depended in part on whether AHP was able to obtain preliminary FDA approval to market its generic K-Dur product.

44. The value to AHP of the license to the '743 patent contained in the Settlement Agreement depended in part on when AHP was able to obtain preliminary FDA approval to market its generic K-Dur product.

45. The fact that AHP and/or Schering may have preferred entering into the Settlement Agreement to continuation of the Patent Infringement Litigation does not by itself establish that the Settlement Agreement harmed competition.

46. The Pitofsky Speech stated that "The agreements thus acted as corks in a bottle, precluding competition not only by the generic company that was paid not to challenge the branded pharmaceutical, but also by other potential generic competitors because the 180 day period does not begin to run until the generic comes to market."

47. The Pitofsky Speech was accurate when it stated that "The agreements thus acted as corks in a bottle, precluding competition not only by the generic company that was paid not to challenge the branded pharmaceutical, but also by other potential generic competitors because the 180 day period does not begin to run until the generic comes to market."

48. The Leary Speech stated that "Since Geneva's agreement not to launch its product meant that the 180-day exclusivity period would not expire, the effect of this provision in the agreement was to ensure that no other company's generic terazosin HCL product could obtain FDA approval and enter the market during the term of the agreement."

49. The Leary Speech was accurate when it stated that "Since Geneva's agreement not to launch its product meant that the 180-day exclusivity period would not expire, the effect of this provision in the agreement was to ensure that no other company's generic terazosin HCL product could obtain FDA approval and enter the market during the term of the agreement."

50. The FTC Testimony stated that "Geneva's agreement not to launch its product meant the 180-day exclusivity period would not begin to run."

51. The FTC Testimony was accurate when it stated that "Geneva's agreement not to launch its product meant the 180-day exclusivity period would not begin to run."

52. No Commissioner or member of the Commission staff has publicly disavowed the accuracy of the portions of the Pitofsky Speech, the Leary Speech, or the FTC Testimony quoted above in Paragraphs 46 through 51.

53. Under the Hatch-Waxman Act, Upsher is entitled to 180 days of marketing exclusivity for its generic version of K-Dur 20.

54. AHP is barred from marketing its generic version of K-Dur 20 until expiration of Upsher's 180-days of marketing exclusivity.

55. The Leary Speech stated that "But, had the case gone to trial, it would have been necessary to contrast the world that the parties created by the challenged agreement and the 'but for' world that would have existed in the absence of the agreement."

56. The Leary Speech was accurate when it stated that "But, had the case gone to trial, it would have been necessary to contrast the world that the parties created by the

challenged agreement and the 'but for' world that would have existed in the absence of the agreement."

57. The Abbott Consent permits Abbott, in certain circumstances, to be a party to a agreement in which an NDA holder provides something of value to an alleged patent infringer and the alleged patent infringer agrees to refrain during part or all of the course of patent infringement litigation from selling the drug at issue in the litigation.

58. The Hoechst Consent permits Hoechst, in certain circumstances, to be a party to a Agreement in which an NDA holder provides something of value to an alleged patent infringer and the alleged patent infringer agrees to refrain during part or all of the course of patent infringement litigation from selling the drug at issue in the litigation.

59. The Abbott Consent does not prohibit Abbott from entering into agreements settling patent infringement litigation between an NDA holder and an alleged infringer in which the parties agree to dismiss the patent infringement litigation, the NDA holder provides something of value to the alleged infringer, and the alleged infringer agrees to refrain from marketing the drug at issue in the litigation for some period of time.

60. The Hoechst Consent does not prohibit Hoechst from entering into agreements settling patent infringement litigation between an NDA holder and an alleged infringer in which the parties agree to dismiss the patent infringement litigation, the NDA holder provides something of value to the alleged infringer, and the alleged infringer agrees to refrain from marketing the drug at issue in the litigation for some period of time.

61. The '743 patent expires on September 5, 2006.

62. The Settlement Agreement granted to AHP a royalty-free license under the '743 patent effective January 1, 2004.

63. Schering was the net recipient of the value that flowed between Schering and AHP in the Settlement Agreement and European License Agreement, collectively.

64. AHP was not the net recipient of the value that flowed between Schering and AHP in the Settlement Agreement and European License Agreement, collectively.

65. The $15 million payment contemplated to be made by Schering to AHP pursuant to the European License Agreement was a fee for the rights granted to Schering pursuant to the European License Agreement.

66. The $15 million payment contemplated to be made by Schering to AHP pursuant to the European License Agreement was not consideration to delay AHP's entry into the market with its generic version of K-Dur 20.

67. At the time of execution of the European License Agreement, the expected value to Schering of the European License Agreement may have been substantial.

68. At the time of execution of the European License Agreement, the expected value to Schering of the European License Agreement may have exceeded its expected value to AHP.

69. At the time of execution of the European License Agreement, the expected value to Schering of the European License Agreement may have exceeded its expected value to any alternative licensee.

70. The Release of Claims and Covenant Not to Sue contained in sections 2.1 and 2.5, respectively, of the Settlement Agreement, had value to Schering.

71. ESI filed an answer to the complaint in the Patent Infringement Litigation in which it asserted a counterclaim and affirmative defenses.

72. At the time of the Settlement Agreement, it was not assured that Schering would be required to pay to AHP any of the payments described in Paragraph 4.1(b) of the Settlement Agreement.

73. At the time of the Settlement Agreement, it was possible that Schering would not be required to pay to AHP any of the payments described in Paragraph 4.1(b) of the Settlement Agreement.

74. If Schering did not make a payment to AHP that exceeded the expected value, at the time of execution of the Settlement Agreement, of Schering's avoided litigation costs and the European License Agreement, there is no basis for concluding that AHP's entry as a supplier of a generic version of K-Dur 20 was delayed by the Settlement Agreement.

75. You have not determined the amount of profits that AHP expected to earn from the sale of its generic version of K-Dur 20.

76. You have not determined the amount of profits that Schering expected AHP to earn from the sale of AHP's generic version of K-Dur 20.

77. Sale by AHP or any other supplier of a generic version of K-Dur 20 would be unlikely to cause a decline in the price of K-Dur 20.

78. Sale by AHP or any other supplier of a generic version of K-Dur 20 would be unlikely to cause a significant decline in the price of K-Dur 20.

79. If AHP were to be the second or later seller of a generic version of K-Dur 20, a significant share of its profits likely would come from sales that were diverted from the first and other prior sellers of generic versions of K-Dur 20.

Respectfully submitted,

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Dated: August 30, 2001

CERTIFICATE OF SERVICE

I hereby certify that this 30th day of August, 2001, I caused an original, one paper copy and an electronic copy of American Home Product Corporation's First Set of Requests for Admissions to Federal Trade Commission to be filed with the Secretary of the Commission, that two paper copies were served by hand delivery upon the Honorable D. Michael Chappell, Administrative Law Judge, and that the following persons were served with one paper copy by hand delivery and an electronic version by email:

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